UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANT'S OPPOSITION TO PLAINTIFFS' STEERING COMMITTEE'S MOTION TO COMPEL PRODUCTION OF SALES REPRESENTATIVE FILES

Defendant Ethicon, Inc. ("Defendant"), by and through counsel, requests that the Court deny Plaintiffs' Motion to Compel Production of Sales Representative Files (Doc. 730) (hereinafter "Plaintiffs' Motion"), and states as follows:

I. INTRODUCTION

As reflected in this Court's prior Order (PTO #41), after negotiation and compromise the Defendant and Plaintiffs agreed to appropriately limit Defendant's production obligations to the custodial files of sales representatives who actually called on bellwether Plaintiffs' treating physicians. Despite this freely negotiated agreement, Plaintiffs now ask this Court to order Defendant to produce the custodial files of all of Ethicon's sales representatives who sold the pelvic mesh products at issue in this litigation at any time since their introduction beginning in 1998. Clearly having failed to find the "smoking gun" in the custodial file for the 129 sales representatives that actually had contact with Plaintiffs' treating physicians, Plaintiffs ask this Court to authorize a true fishing expedition violating all proportionality guidelines embodied in Rule 26. Any such discovery would utterly defeat the efficiencies of focusing on bellwether Plaintiffs at this stage of the litigation.

Accordingly, Plaintiffs' request should be denied for at least two reasons: First, the parties agreed in PTO 41 to an appropriately tailored discovery production that reflected the balancing of interests required by Rule 26. Defendant has complied with that order. Second, requiring the production of additional sales representative files beyond the bellwether Plaintiffs violates the proportionality requirements of Rule 26. As detailed below, such production would create an enormous time and financial burden on Defendant with little likelihood of producing information relevant to Plaintiffs' cases.[1]

This is particularly true where Plaintiffs' request is primarily based on their erroneous assumption that Ethicon's sales representatives keep detailed call notes concerning their interaction with treating physicians. As detailed below, Plaintiffs' error is based on their confusion of pharmaceutical sales with medical device sales. In reality, medical device sales are focused on point of use as opposed to pharmaceutical sales which are focused at the point of the prescription. Accordingly, the industries are very different and, despite Plaintiffs assertions, call notes would generally not be expected to exist for these devices in the way that they believe they do. Plaintiffs' motion should be denied.

II. LEGAL STANDARD[2]

Federal Rule of Civil Procedure 26 provides that the "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed.R.Civ.P. 26(b)(1). While discovery rules are to be accorded a broad treatment to effect their

[1] Plaintiffs' "compromise" position to allow a rolling production of at least another 100 sales representatives is equally unreasonable for the same reasons. PTO 41 balanced the proportionality considerations as required by Rule 26, limiting production to the bellwether Plaintiffs treating physicians. There is no justification to go beyond this limitation – whether it's 100 sales representatives more or 300 more.

[2] Plaintiffs pledge not to "inundate" the Court with case law concerning the scope of discovery. Presumably, Plaintiffs avoid discussing the legal standard because it is clear that the Federal Rules of Civil Procedure and the case law do not support the unbridled fishing expedition that Plaintiffs propose. In contrast, Ethicon does not shy away from the applicable legal standard because, as set forth below, it employs standards of proportionality that Plaintiffs wholly ignore.

purpose of adequately informing the litigants in civil trials, *Herbert v. Lando*, 441 U.S. 153, 177 (1979), a litigant may not use discovery requests to annoy, embarrass, oppress, or cause an undue burdenor expense to his opposing party. *See* Fed.R.Civ.P. 26(c)(1). Additionally, the Court has "substantial discretion" to grant or deny motions to compel discovery. *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Va.*, Inc., 43 F.3d 922, 929 (4th Cir.1995).

Notably, Rule 26(b)(2)(C) requires the Court, on motion or on its own, to limit discovery to insure that it is proportional to what is in dispute in the litigation. Fed.R.Civ.P. 26(b)(2)(C). *See generally Mancia v. Mayflower Textile Servs. Co.*, 253 F.R.D. 354 (D.Md.2008). Indeed, before ordering a party to respond to a discovery request, Rule 26(b)(2)(C) *requires* the Court to engage in a proportionality analysis and to limit the frequency or extent of discovery otherwise allowed by Rule 26 if it determines that:

> (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
>
> (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
>
> (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

Fed.R.Civ.P. 26(b)(2)(C)(i)-(iii).

In the present case, Plaintiffs' overbroad request to require production of all sales representatives' custodial files not only strains the bounds of relevancy, but also clearly fails this proportionality analysis.

III. ANALYSIS

A. Based on the Facts of this Case, Pretrial Order 41 Appropriately Limited Discovery to Sales Representatives Who Called on Bellwether Plaintiffs' Treating Physicians.

By order of the court, over 9,535 plaintiffs' cases have been consolidated into this one multidistrict litigation. In order to efficiently manage this complex litigation, 30 bellwether plaintiffs were originally selected by mutual agreement of the parties. Also by mutual agreement of the parties, this Court entered Pretrial Order 41 ("PTO 41") limiting Defendant's production obligations to the custodial files of sales representatives who actually called on bellwether Plaintiffs' treating physicians. This freely negotiated agreement reflects the need to focus discovery on the issues directly relevant to Plaintiffs' claims in light of the allegations and reality of the factual landscape.

In relation to sales representatives, the actual factual landscape starkly contrasts Plaintiffs' distorted representation of both the discovery that has occurred and the relevancy of their current requests. Plaintiffs' pure speculation that discovery regarding the sales representatives who had no contact with Plaintiffs or their treating physicians somehow might possibly produce evidence of some over-arching company plan is an insufficient basis upon which to grant the extensive discovery sought in this Motion. As directed by PTO 41, Defendant has produced over 290 custodial files, including the available custodial files of the 129 sales representatives associated with the initial 30 bellwether Plaintiffs' treating physicians.[3] Finding no evidence of their

[3] As Plaintiffs note, some of the custodial files for the 129 sales representative associated with the bellwether plaintiffs cannot be located. The present motion is not the appropriate platform for addressing this issue, which Ethicon brought to Plaintiffs' attention and continues to investigate. This issue is irrelevant here because the question before the Court is whether documents from a different group of sales reps -- sales reps who had *no* involvement with Plaintiffs or their treating physicians -- are discoverable under Fed. R. Civ. P. 26. Plaintiffs raise this issue only to prejudice Ethicon before it can be fully heard on this issue at the appropriate time.

alleged company-wide policy of "negligence", "fraud" or the "failure to properly train", (Plaintiffs' Motion at 2), in the nearly ten million pages of company documents and sales representative files already produced, Plaintiffs now seek the files of hundreds of more sales representatives who have no relation to Plaintiffs or their treating physicians.

Defendant's agreement in PTO 41 to limit the production to sales representatives who actually called on Plaintiffs' treating physicians was more than appropriate in light of the role of sales representatives in Defendant's medical device sales. Although Plaintiffs ignore the fact, the pharmaceutical industry and the medical device industry are different both in how they are regulated and in how they function. (Declaration of Matthew Henderson at ¶5, Ex. 1 hereto). Because the industries are very different, the types of documents created by sales representatives in those industries differ. *Id.* The primary function of a pharmaceutical sales representative is to create brand awareness among prescribing physicians in a market. *Id.* Accordingly, pharmaceutical sales are focused on brand impressions and it is thus critical in the pharmaceutical industry to track the frequency of interactions between sales representatives and specific physicians, as well as the brand information communicated. *Id.* The way in which these interactions are tracked is through contemporaneous notes. *Id.* These notes are commonly known in the pharmaceutical industry as "call notes" and are commonly implemented in the pharmaceutical industry. *Id.*

In contrast, the medical device market is smaller and more defined than the pharmaceutical industry. *Id.* at ¶6. Medical devices are not sold to doctors, but to the facilities at which surgeries take place. *Id.* Thus, the primary function of a medical device sales

---

Second, the fact that some materials may have been lost over the numerous years that these products have been on the market from sales representatives who are at issue does not justify reaching out to hundreds of other sales representatives who are not at issue.

representative, unlike that of a pharmaceutical representative, is generally to provide support for products used by the company's accounts, which typically are hospitals. *Id.* Tracking the identity and number of people with which the medical device sales representative interacts at a particular facility on a daily basis is not required for business purposes. *Id.* Rather, tracking generally is directed at customer loyalty by monitoring the sales to the accounts, which are the facilities or hospitals. *Id.*

Thus, unlike the highly regulated sales representatives in the pharmaceutical industry who regularly "detail" physicians and are required to keep detailed notes of their communications with physicians, medical device sales representatives lack such requirements and generally are not trained to keep detailed notes of communications. *Id.* at 5-7. Plaintiffs' assumptions to the contrary lack any factual basis, and are instead based on an erroneous conflation of pharmaceutical sales with medical device sales.

Ethicon's production of sales representative files to date is consistent with this factual backdrop. Ethicon's medical device sales representatives have not been directed to keep call notes with respect to the Stress Urinary Incontinence and Pelvic Organ Prolapse pelvic mesh products, and there has not been a central repository or database for the sales representatives to enter call notes. *Id.* at ¶7. Although it is possible that some sales representatives may have independently kept some form of notes, it has not been a standard practice, requirement, or policy of Ethicon for sales representatives to maintain a record of meetings between sales representatives and physicians. *Id.* In addition, with respect to marketing materials, Ethicon sales representatives generally do not independently create marketing or promotional materials to provide to physicians. *Id.* at ¶8. Instead, the materials that they provide to physicians generally go through the copy review process and are standardized across a particular product. *Id.* The

uniform set of materials available for sales representatives to utilize with physicians are made available to all Ethicon sales representatives. *Id.*

Accordingly, there is no plethora of "call notes" because, unlike the requirements in the pharmaceutical industry that Plaintiffs erroneously rely upon, Ethicon's sales representatives are not required or trained to create them. The production of approximately 300 or more[4] sales representative files will not change this fact. Plaintiffs request permission to conduct a fishing expedition in a barren lake. In light of the unlikelihood of finding relevant, non-cumulative information in additional files, PTO 41 appropriately limits production to those sales representatives that actually called on Plaintiffs' treating physicians.

Plaintiffs also argue that wholesale production of the custodial files for sales representatives would somehow support a pattern and practice allegation that would lead to a gross negligence/punitive damages claim, as well as demonstrate how physicians were trained. What Plaintiffs fail to mention is that none of this purported conduct would in any way relate to any of the bellwether Plaintiffs that are set for trial. Therefore, even if Plaintiffs were to find what they are looking for, it would not be relevant to the specific Plaintiffs at issue and the discovery should therefore not be addressed at this time.

Finally, Plaintiffs argue that a wholesale production of materials from unrelated sales representatives would somehow establish Ethicon's knowledge of adverse events. This argument is similarly flawed because the sources of Ethicon's knowledge of adverse events are found in the source materials for the adverse event reports – all of which have been produced. A

[4] Ethicon is currently in the process of identifying the universe of additional sales representatives from whom it would have to collect documents, which itself is burdensome. The number 300 is a conservative, good-faith approximation of the number of such sales representatives, and the number could be higher. (Decl. of J. Hewett, Ex. 2 hereto.)

random document that a sales representative may have in his or her file has no bearing on the reporting of adverse events.

B. Producing Additional Sales Representatives' Custodial Files is not Proportional Under Rule 26.

Even in the unlikely event that Plaintiffs' requests for hundreds more sales representative files were likely to lead to some marginally relevant, non-cumulative information, their request is not proportional under Federal Rule of Civil Procedure 26(b)(2)(C)(iii). A party need not produce documents if "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of discovery in resolving the issues." Fed. R. Civ. P. 26(b)(2)(C)(iii).

This rule "cautions that all permissible discovery must be measured against the yardstick of proportionality." *In re C.R. Bard, Inc. Pelvic Repair Systems Product Liability Litigation* Slip Copy, 2013 WL 1722998S.D.W.Va.,2013 (quoting *Lynn v. Monarch Recovery Management, Inc.*, 285 F.R.D. 350, 355 (D.Md.2012); *Victor Stanley, Inc. v. Creative Pipe, Inc.*, 269 F.R.D. 497, 523 (D.Md.2010)). "Both the Supreme Court and the Federal Rules of Civil Procedure Advisory Committee have emphasized the importance of the 26(b)(2)(C) proportionality limit on fair and efficient operation of discovery rules." *Dongguk Univ. v. Yale Univ.*, 260 F.R.D. 70, 73 (D.Conn.2010).[5]

[5] The changes made to Rule 26 emphasize the importance of this balancing process and how, absent such a process, discovery can be abused. The issue of discovery abuse was a major concern at the American Bar Association's Conference held in August 1976. *American Bar Association Report of Pound Conference Follow-Up Task Force*, 74 F.R.D. 159 (1976). The American Bar Association noted that allegations of discovery abuse were widespread and that this alleged abuse was increasing litigation costs, unduly delaying adjudication and coercing unfair settlements. *Id*. at 191. It recognized the very real concern that the "discovery process [was] being overused" and that "[w]ild fishing expeditions, since any material which might lead to the discovery of admissible evidence is discoverable, seem to be the norm." *The Pound Conference Recommendations: A Blueprint For The Justice System in the Twenty-First Century*, 76 F.R.D. 277, 288 (1978). Federal Rule 26 was amended in 1983 to curb this growing problem. The Advisory Committee Notes to the 1983 Amendment recognized that given "our adversary tradition

To date, approximately 1.5 million documents, comprising approximately 10 million pages, have been produced in connection with this litigation. (Decl. of J. Hewett, Ex. 2 hereto.) This collection and production process has been ongoing for approximately two years, and has included collections from a wide range of electronic and paper sources from over 225 current or former Ethicon employees. (*Id*.) In addition, significant volumes of documents were collected from general sources such as group and departmental file shares, databases, and warehouse storage facilities. The collections occurred both in and outside the United States. (*Id*.)

In addition, responsive materials, to the extent that they are available, were collected and produced from approximately 130 sales representatives. (Decl. of J. Hewett, Ex. 2 hereto.) The collection process involved the coordinated efforts of a number of third-party vendors, in-house IT resources, as well as in-house and outside legal counsel. Once collected, the documents were processed and went through a multistep review prior to production. (*Id*.)[6]

Separate and apart from the above-described documents, Ethicon has asked its vendor to estimate the resources and costs to collect, process, review, and produce documents in this litigation from approximately 300 additional sales representatives located throughout the

---

and the current discovery rules, it is not surprising that there are many opportunities, if not incentives, for attorneys to engage in discovery that, although authorized by the broad, permissive terms of the rules, nevertheless results in delay." The 1983 amendments to Rule 26 were purposely made to "confront the problem of over-discovery and to allow the court to proportion discovery, even though it may be relevant." *Nestle Foods Corp. v. Aetna Cas. and Sur. Co*., 135 F.R.D. 101, 107 (D.N.J. 1990). The proposed amendments continue to make efforts to address this ever-growing problem. *See* Report of the Advisory Committee on Civil Rules at 9-12 (May 8, 2013)(proposing additional amendments to Rule 26 reflecting continuing need to focus on proportionality and cost-benefit analysis in limiting discovery abuses);Proposed Amendments Published for Public Comment, found at http://www.uscourts.gov/RulesAndPolicies/rules/proposed-amendments.aspx

[6] In addition to the approximately 1.5 million documents discussed above, Ethicon also searched a number of enterprise database system materials and produced native files, including but not limited to clinical study data and complaint file data. Upon information and belief, to date Ethicon has spent over $15 million so far on the collection, processing, hosting, review, and production of the materials from Ethicon and from sales representatives described above. (Decl. of J. Hewett, Ex. 2 hereto.)

country. (Decl. of J. Hewett at ¶¶16-20 Ex. 2 hereto.) To complete the collection, processing, review, and production of such documents, a substantial team of attorney reviewers from an outside vendor, as well as project managers and consultants, would have to be utilized. (*Id*.) It is Ethicon's estimate that, exclusive of attorneys' fees, the total cost to perform collections from the approximately 300 additional sales representatives, and to process, review, and produce the documents, would be between $500,000 and $1 million. (*Id*.) Additionally, it would take an estimated four to six months to collect, process, and for review the files for an additional 300 sales representatives. (*Id*.)

As reflected in Rule 26, a "trial court has a duty of special significance in lengthy and complex cases where the possibility of abuse is always present, to supervise and limit discovery to protect parties and witnesses from annoyance and excessive expense." *Dolgow v. Anderson*, 53 F.R.D. 661, 664 (E.D.N.Y. 1971). *See, e.g.*, *Munoz-Santana v. United States*, 742 F.2d 561 (9th Cir. 1984) (district court abused its discretion in entering the discovery order because the cost of further production was not warranted by the plaintiff's need for the records where producing party's computer system was not indexed in such a way to permit easy retrieval of relevant files; files would therefore have to be searched by hand. The court recognized the cost of complying with the discovery order, either by hand search or by improving the computer filing system was substantial).

Some discovery necessarily must be foregone or structured in complex litigation if massive cases are to be resolved expeditiously or, as with this case, ever to be tried. Here Ethicon's burden in complying with Plaintiffs' new request for all former and current sales representative files far outweighs any need Plaintiffs have for additional records. The resources required to be diverted from other requested or mandated discovery will be substantial and will necessarily slow down ongoing discovery projects of more relevance to the impending trials and

this litigation. Plaintiffs have received all available non-privileged sales representative files relating to the bellwether Plaintiffs treating physicians. This production, as reflected in PTO 41, reflected the proper balancing of efficiencies, need, and burden as required by Rule 26. In light of the unlikely relevance of the information sought, balanced against the burden and expense of production, this Court should deny Plaintiffs' Motion.

C. If the Court Allows Any Additional Discovery, Plaintiffs Should be Required to Pay for It.

To the extent the Court allows Plaintiffs to pursue additional sales representative files for representatives that have had no contact with Plaintiffs' treating physician, it should – at the very least – require them to bear the significant cost of that discovery. As the Supreme Court has explained, "[u]nder th[e] [discovery] rules, the presumption is that the responding party must bear the expense of complying with discovery requests, but he may invoke the district court's discretion . . . to grant orders protecting him from 'undue burden or expense' in doing so, including orders conditioning discovery on the requesting party's payment of the costs of discovery." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 358 (1978). Consistent with this ruling, courts have held that "where the cost of producing documents is very significant, [a district court] has the power to allocate the cost of discovery" to the requesting party "and doing so is fair." *Boeynaems v. LA Fitness Int'l LLC*, 285 F.R.D. 331, 335 (E.D. Pa. 2012) (ordering plaintiffs to pay cost of additional discovery beyond the hundreds of thousands of documents already produced by the defendant; "given the large amount of information [d]efendant has already provided, [p]laintiffs need to assess the value of additional discovery" and decide whether it is truly worth the cost to them); *see also Rowe Entm't, Inc. v. William Morris Agency, Inc.*, 205 F.R.D. 421, 430-32 (S.D.N.Y. 2002) (plaintiffs seeking discovery of defendants' email archives were required to bear the cost of that discovery because "plaintiffs' demands . . . [were]

extremely broad," the "marginal value of searching the e-mails [was] modest at best," and the "costs of the proposed discovery would be substantial by any definition"); *Wiginton v. CB Richard Ellis, Inc.*, 229 F.R.D. 568, 577 (N.D. Ill. 2004) (ordering party requesting discovery to bear the majority of discovery costs in light of the limited likelihood that the broad discovery sought would unearth critical information and the high cost of production); *Schweinfurth v. Motorola, Inc.*, No. 1:05CV0024, 2008 U.S. Dist. LEXIS 82772, at *6-7 (N.D. Ohio Sept. 30, 2008) (ordering proposed class action plaintiffs to share cost of the additional discovery they sought where "over 200,000 pages of documents" had already been produced by the defendant and the additional information sought was "immense" in scope).

Any additional sales representative discovery in this litigation should be subject to such cost shifting. As set forth above, Ethicon has spent substantial time and money responding to plaintiffs' discovery requests, ultimately resulting in the production of millions of pages of documents related to Ethicon's pelvic mesh products. Nonetheless, plaintiffs contend that this production is insufficient, and that Ethicon should also be required to locate, collect, review and produce additional documents for representatives with no direct ties to Plaintiffs. Ethicon estimates that such an undertaking would cost the Company between $500,000 and $1 million to complete. There is simply no justification for saddling Ethicon with the significant financial burden that would be imposed by this additional, duplicative and irrelevant discovery.

IV. CONCLUSION

In accordance with the foregoing, Ethicon respectfully requests that Plaintiffs' motion be denied.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas
David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

/s/ Christy D. Jones
Christy D. Jones
Butler, Snow, O'Mara, Stevens & Cannada, PLLC
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on September 10, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas
David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

/s/ Christy D. Jones
Christy D. Jones
Butler, Snow, O'Mara, Stevens & Cannada, PLLC
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523